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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,449	08/25/2003	Mann Satyanarayana Reddy	BULK 3.0-026	1649

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DR. REDDY'S LABORATORIES, INC.
200 SOMERSET CORPORATE BLVD
SEVENTH FLOOR,
BRIDGEWATER, NJ 08807-2862

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/647,449

Applicant(s)

REDDY ET AL.

Examiner

Celia Chang

Art Unit

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) 1-57 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Dec. 5, 2005 have been entered and considered carefully.
2. The rejection of claims 38, 40-48 under 35 USC 102(b) over US 5,312,924 is maintained for reason of record.

Please note that it is well known in the art that there is only one amorphous product of a given material. (see Ulicky comprehensive dictionary of physical chemistry, p. 21, it was disclosed that solid can be subdivided into crystalline or amorphous. See concise encyclopedia chemistry, where it was defined that multiple crystalline forms are called polymorphs). Any x-ray diffraction of an amorphous material is only to show no diffraction or non-crystalline. Therefore, the incorporation of x-ray diffraction into the base claim does not change the product and anticipation is found. It was an oversight that claim 39 was not included in the rejection and correction is now made.

3. The rejection of claims 1, 34-35 under 35 USC 102(b) over US 5,132,924 is maintained for reason of record. Applicants argued that the incorporation of X-ray diffraction pattern obviated the anticipation. Please note that, the finding of anticipation is whether the claims and the prior art are "same identical" product not what physical parameters are used in claiming them. In so far as the instant claims are concern, to the extend the identifier being IR, the instant product and the prior art products are essentially the same i.e. compare figure 4 and combined part I and II of figure 2-3 of US 5,132,924, thus, same product. As it was clearly delineated in the previous office action no evidence in the record showing that the instant crystalline form and the prior art A, B, or C are different especially when the IR are essentially the same and it was clearly disclosed in the specification although 2 theta values and d-spacing are useful in identifying different crystalline forms, margin of error existed (see page 16, specification). Therefore, the single 2 theta pattern does not demarcate any product from another without multiple identifiers which when compared two forms clearly can demarcate each to be different products given margin in error.

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4. The rejection of claims 1-37, 39, 50-57 under 35 USC 103(a) over Grell '924 in view of Grell and Brittain is maintained for reason of record.

Even if, in *argue* do, the X-ray diffraction pattern is different from the product of the prior art, it is "*in the strictest sense,the same pure substance....*" of the prior art, i.e. *prima facie* obvious unless some form of unobviousness can be provided (see Brittain p.185). The mere difference in physical parameter such as X-ray diffraction pattern does not offer any unexpected advantage of prior art product with the same chemical property and biological property i.e. a mere variation in physical forms.

5. The rejection of claims 8-18 under 35 USC 112 first paragraph for lacking sufficient description and enabling support of the claims is maintained for reason of record.

Applicants argued that claim 8 as amended provides a composition comprising (S)-repaglinide as a solid wherein at least 80% by weight of said solid is in crystalline form III, in fact supports the rejection. The transformation of the form III to other forms indicated the metastable nature of Form III. Further more, the article provided by applicants clearly stated that composition maintaining the particular form is far from routine but may cost millions of dollars and effort to obtain (see p. 2 disappearing act). Therefore, absent of *any description or enablement* that the particular form or X-ray can be obtained in a "composition", the deficiency of description and enablement as compared to the art standard described in applicants' article *tricky business*, is self evident.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

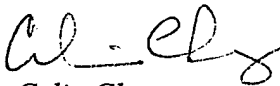
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Mar. 2, 2006


Celia Chang
Primary Examiner
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